



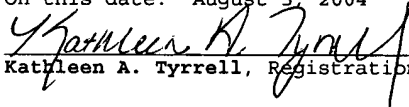
IFW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No.: KBI-0022
Inventors: Ranganathan et al.
Serial No.: 10/803,211
Filing Date: March 18, 2004
Examiner: Not Yet Assigned
Group Art Unit: 1651
Title: Methods of Improving or Augmenting
Kidney Function

I, Kathleen A. Tyrrell, Registration No. 38,350,
certify that this correspondence is being deposited
with the U.S. Postal Service as First Class mail in
an envelope addressed to the Commissioner for Patents
P.O. Box 1450, Alexandria, VA 22313-1450

On this date: August 5, 2004


Kathleen A. Tyrrell, Registration No. 38,350

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

(XX) In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified application, within three months of the date of entry into

the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, no additional fee is required.

() In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, therefore:

() Certification in Accordance with §1.97(e) is attached hereto; or

() Authorization to charge Deposit Account No. 50-1619 the fee of \$180.00 as set forth in §1.17(p) is provided.

() In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee, therefore included are: Certification in Accordance with §1.97(e); Petition Requesting Consideration of the Information Disclosure Statement; and the fee of \$130.00 as set forth in §1.17(I) (1).

() Copies of each of the references listed on the attached Form PTO-1449 (modified) are enclosed herewith.

(XX) In accordance with §1.98(d), copies of some or all of the references listed on the attached Form PTO-1449 (modified)

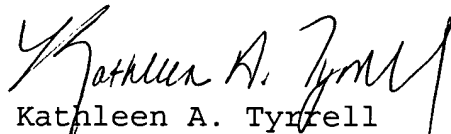
are not enclosed herewith because they were previously submitted to the U.S. Patent and Trademark Office in prior applications Serial No. 09/557,011 filed April 20, 2000, Serial No. 09/855,346, filed May 15, 2001, Serial No. 10/689,359, filed October 20, 2003, for which a claim for priority under 35 U.S.C. §120 has been made in the instant application.

Please charge any deficiency or credit any overpayment to Deposit Account No. 50-1619. This form is submitted in duplicate.

() The relevance of the listed references in a foreign language is as stated in the specification at pages @@.

(XX) All listed references are in the English language.

Respectfully submitted,

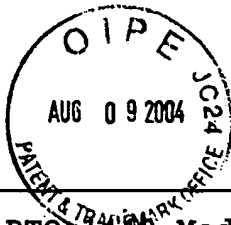


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Date: August 5, 2004

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Sheet 01 of 07

Form PTO-1419 Modified		Docket No. KBI-0022	Serial No. 10/803,211
List of Patents and Publications Cited by Applicant (Use several sheets if necessary)		Applicant Natarajan Ranganathan	
		Filing Date March 18, 2004	Group 1651
U.S. Department of Commerce			
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)			
	CA	Marteau et al., "Protection from gastrointestinal diseases with the use of probiotics ¹⁻³ ", Am. J. Clin. Nutr. 2001 73(suppl):430S-436S	
	CB	Holzapfel et al., "Overview of gut flora and probiotics", International Journal of Food Microbiology 1998 41:85-101	
	CC	von Wright et al., "Probiotics:established effects and open questions", Eur J Gastroenterol Hepatol 1999 11(11):1195-1198	
EXAMINER		DATE CONSIDERED	

Form PTO-1449 Modified List of Patents and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce		Docket No. KBI-0022	Serial No. 10/803,211
		Applicant Ranganathan et al.	
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)			
	AA	Bliss et al., "Supplementation with gum arabic fiber increases fecal nitrogen excretion and lowers serum urea nitrogen concentration in chronic renal failure patients consuming a low-protein diet ¹⁻⁴ ", <i>Am. J. Clin. Nutr.</i> 1996 63 :392-398	
	AB	Chang, T.M.S., "Artificial Cells", Chapter 5, in <i>Biomedical Applications of Microencapsulation</i> , edited by Lim, F. CRC Press Florida, pp 86-100	
	AC	Clark et al., "Perfusion of Isolated Intestinal Loops in the Management of Chronic Renal Failure", <i>Trans. Am. Soc. Artif. Intern. Organs</i> 1962 8 :246-251;	
	AD	Dunn et al., "Gas Chromatographic Determination of Free Mono-, Di-, and Trimethylamines in Biological Fluids", <i>Analytical Chemistry</i> 1976 48 :41-44	
	AE	Einbacher and Carter, "The Role of the Microbial Flora in uremia", <i>J. Exp. Med.</i> 1966 123 :239-250	
	AF	Friedman et al., "Hypertriglyceridemia Responsive to Charcoal Sorption", <i>Proc. Clin. Dia. Trans. Forum</i> 1977 7 :183-184	
	AG	Goldenhersh et al., "Effect of microencapsulation on competitive adsorption in intestinal fluids", <i>Kidney Int.</i> 1976 10 :S251-S253	
	AH	Gotch et al., "Theoretical Considerations on Molecular Transport in Dialysis and Sorbent Therapy for Uremia", <i>Journal of Dialysis</i> 1976-1977 1 (2):105-144	
	AI	Kjellstrand et al., "On the Clinical use of Microencapsulated Zirconium Phosphate-Urease for the Treatment of Chronic Uremia", <i>Trans. Am. Soc. Artif. Intern. Organs</i> 1981 27 :24-29	
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	AJ	Kolff, W.J., "Longitudinal perspectives on sorbents in uremia", <i>Kidney Int.</i> 1976 10:S211-S214	
	AK	Nagano et al., "Pharmacological properties of chitosan-coated dialdehyde cellulose (chitosan DAC), a newly developed oral adsorbent (II). Effect of chitosan DAC on rats with chronic renal failure induced by adriamycin", <i>Medline Abstract UI 96058336</i> 1995	
	AL	Niwa et al., "Indoxyl Sulfate and Progression of Renal Failure: Effects of a Low-Protein Diet and Oral Sorbent on Indoxyl Sulfate Production in Uremic Rats and undialyzed Uremic Patients", <i>Miner. Electr. Metab.</i> 1997 23:179-184	
	AM	Okada, K. and Takahashi, S., "Correction by oral adsorbent of abnormal digestive tract milieu in rats with chronic renal failure", <i>Nephrol. Dial. Transplant.</i> 1995 10(5):671-676	
	AN	Owadu, A. and Shiigai, T., "Effects of Oral Adsorbent AST-120 Concurrent with a Low-Protein Diet on the Progression of Chronic Renal Failure", <i>Am. J. Nephrol.</i> 1996 16(2):124-127	
	AO	Prakash, S. and Chang, T.M.S., "Microencapsulated genetically engineered live <i>E. coli</i> DH5 cells administered orally to maintain normal plasma urea level in uremic rats", <i>Nature Med.</i> 1996 2:883-887	
	AP	Prakash, S. and Chang, T.M.S., "Preparation and In Vitro Analysis of Microencapsulated Genetically Engineered <i>E. Coli</i> DH5 Cells for Urea and Ammonia Removal", <i>Biotechnology and Bioengineering</i> 1995 46:621-626	
	AQ	Setala, K., "Bacterial enzymes in uremia management", <i>Kidney Intl Suppl.</i> 1978 8:S194-202	
	AR	Shimizu et al., "Removal of uremic waster metabolites (chiefly urea) by chemically surface-treated dialdehyde starch", <i>Chemical Abstracts</i> 1982 97:222903	
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U. S. PATENT DOCUMENTS

Examiner Initial		Document No.	Date	Name	Class	Subclass
	AA	5,032,399	7-16-91	Gorbach et al.	424	93
	AB	5,531,988	7-2-96	Paul	424	93.4
	AC	5,733,568	3-31-98	Ford	424	433
	AD	5,840,318	11-24-98	Marshall et al.	424	282.1

FOREIGN PATENT DOCUMENTS

Examiner Initial		Document No.	Date	Country	Translation YES NO	

EXAMINER

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Form PTO-1449 Modified List of Patents and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce		Docket No. KBI-0022	Serial No. 10/308,211
		Applicant Ranganathan et al.	
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	AA	Asher et al., "Projections and measurements of in vivo performance of liquid membrane capsules", <i>Kidney Int.</i> 1976 10:S-254-S-258	
	AB	Bezkorovainy A., "Probiotics:determinants of survival and growth in the gut ¹⁻³ ", <i>Am. J. Clin. Nutr.</i> 2001 73(Suppl): 399S-405S	
	AC	Bliss et al., "Supplementation with gum arabic fiber increases fecal nitrogen excretion and lowers serum urea nitrogen concentration in chronic renal failure patients consuming a low-protein diet ¹⁻⁴ ", <i>Am. J. Clin. Nutr.</i> 1996 63:392-398	
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	AE	Chang T.M.S., "Assessments of clinical trials of charcoal hemoperfusion in uremic patients", <i>Clin. Neph.</i> 1979 11:111-119	
	AF	Clark et al., "Perfusion of Isolated Intestinal Loops in the Management of Chronic Renal Failure", <i>Trans. Am. Soc. Artif. Intrn. Organs</i> 1962 8:246-251	
	AG	Cummings J.H. et al., "Prebiotic digestion and fermentation ¹⁻³ ", <i>Am. J. Clin. Nutr.</i> 2001 73(Suppl): 415S-420S	
	AH	Dunn et al., "Gas Chromatographic Determination of Free Mono-, Di-, and Trimethylamines in Biological Fluids", <i>Analytical Chemistry</i> 1976 48:41-44	
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	AV	Prakash S. and Chang T.M.S., "Preparation and In Vitro Analysis of Microencapsulated Genetically Engineered E. coli DH5 Cells for Urea and Ammonia Removal", <i>Biotechnology and Bioengineering</i> 1995 46:621-26	
	AW	Setala, K., "Bacterial enzymes in uremia management", <i>Kidney Intl.</i> 1978 8:S-194-S-202	
	AX	Shimizu et al., "Removal of uremic waste metabolites (chiefly urea) by chemically surface-treated dialdehyde starch", <i>Chemical Abstracts</i> 1982 97:222900 3p	
	AY	Sparks R.E., "Gastrosorbents in the therapy of uremia: Inferences from intestinal loop dialysis", <i>Kidney Int.</i> 1975 Suppl 7:S-373-S-376	
	AZ	Twiss E.E. and Kolff W.J., "Treatment of Uremia by Perfusion of an Isolated Intestinal Loop", <i>JAMA</i> 1951 146:1019-1022	
	BA	Yatzidis et al., "Newer oral sorbents in uremia", <i>Clinical Nephrology</i> 1979 11:105-106	
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